GLP-1 RA Analogue: Usage and Guidance Consent

This document is intended to serve as a confirmation of informed consent for the use of GLP-1 RA analogues. Select the product being recommended below:

GLP-1 receptor agonist analogue
GLP-1/GIP receptor agonist analogue
GLP-1/GIP/Glucagon receptor agonist analogue

A. Client Informed Consent

1. I voluntarily request that _____ (provider) consults me for my desired health and wellness goals.
2. I have informed my provider of any known allergies, my medical conditions, medications, social/family history.
3. I have the right to be informed of any alternative options, side effects, and the risks and benefits.
4. I understand the mechanism of action of the product(s) being recommended.
5. I understand how to administer the product(s).
6. I understand the product will come from a lab and/or a compounding pharmacy, and that the product is not FDA approved. I also understand that there is a requirement to consent to my data being used for research purposes, though it will not include any protected health information (no personally identifying information will ever be used for research conducted). This data will be used at the discretion of the provider and/or his/her team that is compiling and interpreting the data points.
7. Prices may vary and change. My charge will include my time with my provider (in person and via communication outside of the office), supplies, and product(s).
8. _____ (provider) may change the pharmacy/lab based on several factors (availability, shipping time, cost). My Provider will tell me as this happens.
9. It has been explained to me that this product could be harmful if taken inappropriately or without advice from the provider.
10. I understand this product may cause adverse side effects (see below). I understand this list is not complete and it describes the most common side effects, and that death is also a possibility of taking this product. I understand symptoms may be worse after there has been a change in my product dose or when first starting use of the product.

Common side effects include, but are not limited to:

- Gastrointestinal: Nausea/vomiting, abdominal pain, Diarrhea/constipation, dyspepsia, abdominal distension, eructation, flatulence, gastroenteritis, GERD, gastritis, lipase increase, amylase increase
- Neurological: Headache, dizziness
- Cardiac: Heart rate increase, Hypotension
- Endocrine: Fatigue, hypoglycemia (diabetic patients), alopecia
- Ophthalmic: Retinal disorder (diabetic patients)
- Skin: redness or pain at injection site

Serious Reactions include, but are not limited to:

- Thyroid C-cell tumor (animal studies)
- Medullary thyroid cancer
- Hypersensitivity reaction
- Anaphylaxis
- Angioedema
- Acute kidney injury

- Chronic renal failure exacerbation
- Pancreatitis
- Cholelithiasis
- Cholecystitis
- Syncope

A. I understand that I have the following responsibilities:

1. I agree to obtain this product only from _____ (provider/clinic) while under his/her care, so as not to inadvertently mix products or variations of products from unknown sources.

2. Medical history: I will tell _____ (provider) my complete medical history, including:allergies, medications, medical/surgical/social/family history.
    a. _____ (provider) may ask to review, with my permission, mymedical history (medications, recent lab results, pertinent imaging results).
    b. I understand that if I become pregnant or start trying for pregnancy, I must stop use of this product.
    c. I will be honest to the best of my ability the history he/she needs to know.
    d. I will tell my provider any updated health information (medication, allergies, personal medical issues/surgeries/social history, or family history changes).
    e. My provider can discuss my treatment plan with any collaborating researcher and/or healthcare provider.
    f. I will always tell other providers about all medications I am taking if/when asked.
    g. _____ (provider) may ask for me to seek additional labs while on treatment to ensure my safety.

1. Directions for use: I will take my product(s) only as recommended according to the directions, led by _____ (provider).
    a. If I feel my products are not effective, or are causing undesirable side effects, I will contact my provider for instructions.
    b. I will not adjust my product dosing without prior instruction to do so.
    c. I understand that the product(s) must be kept refrigerated.
    d. I understand this product must be self-injected in the subcutaneous tissue once weekly (unless my provider prefers to inject me themselves in person). I will not inject any less than 7 days unless directed by _____ (example: travel).
    e. I will not share needles and dispose of needles safely.
    f. If I'm having troubles with the administration of the product(s), I will seek help from _____ (provider).

2. Refills:
    a. All refills will require an appointment.
    b. I understand, I may need to schedule refill appointments ahead of time to avoid delays in refills.
    c. I will not ask for early refills.
    d. I understand that I may be asked to bring the product with me to my appointments to check the quantity left or asses how I am injecting.

3. Safety:
    a. I understand it is important to keep my product away from children (<18 years old)
    b. I am the only one who will use my product(s). I will not give or sell my product(s) to anyone else.

4. If _____ (provider) deems it appropriate to start weaning my product use or transition to maintenance dosing, I will comply.

A. Discontinuation of product use: I understand that _____ (provider) may stop recommending my product(s) if:
    a. I am having unfavorable side effects or it's not working to advance my health and wellness goals
    b. I have been untruthful in my medical or family history
    c. I do not follow through with the recommended plan of care.
    d. I do not follow any parts of "Part B: responsibilities" in this agreement.

I have read this form in its entirety. It has been explained to me. I have had the opportunity to ask questions and have all my questions answered. I fully understand the above information and have no further questions. By signing this form, I voluntarily give my consent for medical consultation, recommendations and application support and agree to the risks.

_____ _____

Patient Signature Date Signed